

Advancing the Adoption of Medical Device "Plug-and-Play" Interoperability to Improve Patient Safety and Healthcare Efficiency

Medical devices are essential for the practice of modern medicine. However, unlike the interconnected "plug-and-play" world of modern computers and consumer electronics, most medical devices are designed to operate independently and do not employ open networking standards for data communication or for device control. The integration of individual medical devices into a patient-centric networked system for the care of a high-acuity patient will support an infrastructure for innovation in patient safety, treatment efficacy, and workflow efficiency by enabling the development of:

- Medical device safety interlocks to produce error-resistant systems
- Clinical decision support requiring real-time integrated clinical parameters and procedural context
- Enhanced sensitivity and specificity of clinical alarm systems through the integration of physiological measurements, equipment status, and contextual information
- Monitoring of device activity and performance
- Automated system readiness assessment (prior to starting invasive clinical procedures)
- Support of remote-ICU surveillance and quality improvements
- "Plug-and-play" modularity to support "hot swapping" of devices
- Physiologic closed-loop control, e.g. of medication, fluid delivery, and ventilation
- Real-time inventory of equipment for asset tracking, maintenance, upgrade, recall, and readiness assessment
- Comprehensive data collection (like a "flight recorder") for the analysis of near-misses and adverse events

Systems of integrated medical devices could support improvements in workflow and reductions in medical errors and healthcare costs to the benefit of patients throughout the continuum of care: from the home, to pre-hospital transport, and to clinical areas as diverse as the OR, ICU, and general hospital ward.

The importance of applying modern systems engineering solutions, such as interoperability, to improve patient safety and reduce costs was addressed in a National Academy of Sciences report entitled *Building a Better Delivery System: A New Engineering/Health Care Partnership*¹. However, cross-vendor standards-based interoperability has not been widely adopted for medical devices. Currently, when medical device integration is required, customized device interfaces must be developed, with high cost and long development time. Further, these customized interfaces are still unable to add essential functionality that was not designed by the manufacturer to be transmitted through the interface (e.g. data required for system readiness assessment and adverse event analysis).

About the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program

The MD PnP program was established in 2004 to lead the evaluation and adoption of open standards and technology for medical device interoperability to support clinical innovation. The program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare Information Systems, with additional support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program

remains clinically grounded. We have taken a multi-faceted approach to begin addressing key barriers to achieving interoperability, including the development and support of suitable open standards (e.g. the Integrated Clinical Environment, or ICE), and the elicitation, collection and modeling of clinical use cases and engineering requirements for the ICE platform and “ecosystem”. Since the program’s inception, more than 600 clinical and engineering experts, and representatives of more than 85 institutions that share a vision of medical device interoperability have participated in ongoing convening activities.

Barriers to the widespread adoption of interoperability have included the absence of industry-adopted interoperability standards for data communication and device integration, and lack of an appropriate “plug-and-play” system architecture (due to emphasis on proprietary, single-source solutions). Moreover, there have been regulatory concerns, liability concerns, and the few available use cases have been poorly articulated. These barriers underscore the need for an integrated clinical environment “ecosystem” that would include system functions such as data logging, data security, device authorization, and connectivity to the hospital information system. These functions would contribute to a complete systems solution that could meet clinical, technical, regulatory, and legal requirements.

The CIMIT MD PnP Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. In the Lab we are developing demonstrations of interoperability-based patient safety improvements, such as improving the safety and quality of portable x-rays, and patient-controlled analgesia systems that are used for pain management. Our geographically dispersed, multidisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Draper Laboratory, FDA, Univ. of Penn. Dept. of Computer and Information Science, Draeger Medical Systems, LiveData Inc., Mitre, DocBox Inc., Univ. of New Hampshire, IXXAT, NIST, NSF, Geisinger Health System, as well as the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare Information Systems). The MD PnP team recently received CIMIT’s 2007 Edward M. Kennedy Award for Healthcare Innovation.

As a result of collaboration with this program, Kaiser Permanente has since 2006 included the following language in vendor contracts:

“Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the ‘Integration Standard’), and ... will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue ... to provide open interfacing protocols ...”

In March 2007 the Anesthesia Patient Safety Foundation issued the following endorsement of interoperability:

“APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind....”

The Board of Directors of the American Society of Anesthesiologists endorsed a similar statement in February 2008. (House of Delegate approval is expected in October 2008.)

Key projects include:

- Eliciting high-level clinical scenarios to define user requirements to drive and inform interoperability solutions. This includes identifying Adverse Events and Near Misses that could have been avoided through the integration of medical devices and IT systems.
- Compiling a repository of interoperability use cases that can be shared
- Developing a clinical requirements acquisition and analysis methodology that enables use case scenarios to be specified at the level of detail needed to derive engineering requirements, including both functional and quality requirements
- Supporting the implementation of open standards to accelerate medical device interoperability, including developing standards for a patient-centric “Integrated Clinical Environment” (ICE) (<http://mdpnp.org/ICE.html>)
- Developing shared contract language to support the preferential acquisition of interoperability standards-conformant systems by healthcare organizations (as implemented by Kaiser Permanente)
- Defining a safe, “least-burdensome” regulatory pathway for patient-centric networked medical devices, in partnership with the U.S. FDA
- Preparing an open ICE research platform to deploy and evaluate reference implementations of proposed standards, technologies, and products

How You Can Participate

- **Clinicians** can contribute clinical scenarios (or “use cases”) to ensure that new interoperability standards and technology will enable meaningful clinical solutions. Diversity of use cases increases the likelihood of effective and generalizable solutions.
- **Engineers** can analyze clinical use cases to generate functional specifications, assess current standards to perform “gap analyses”, and evaluate proposed technologies. Diverse engineering expertise is essential.
- **Healthcare delivery systems** can specify performance requirements, and require adherence to medical device interoperability language in vendor contracts. Widespread adoption of interoperability will happen only when there is recognized consumer demand.
- **Regulatory agencies** can facilitate regulatory clearance of interoperable medical devices, creating new regulatory paradigms as needed.
- **Medical device manufacturers** can participate in the development and adoption of interoperability standards, and partner with the MD PnP Program to develop a shared interoperability testing and use-case demonstration environment.
- **Interoperability promoting organizations** can support revision of existing standards to meet clinical requirements, collaborate on clinical use case implementations in the MD PnP Lab, and ensure that through collaboration we shepherd the adoption of medical device interoperability to empower innovation in the safety and efficiency of health care.

Learn more at <http://www.mdnp.org> or contact us using the information below.

(Follow the link above for streaming video coverage of the entire June 25-27, 2007 conference on MD PnP and HCMDSS.)

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Reference:

1. National Academies Press, 2005, Recommendation 4-3